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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,686	11/28/2001	Klaus During	03528.0133.PCUS00	7122

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/889,686

Applicant(s)

DURING ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-8,10-14,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-8,10-14,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 01 September 2004. Applicant has cancelled claims 3, 5, 15 and 16, and amended claims 1, 4, 6, 10-14, and 17-18. Claims 1, 2, 4, 6-8, 10-14 and 17-18 are pending, and are examined in the instant action.
2. This action is made FINAL necessitated by Applicant's amendment..
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase in claim 11 line 5, "the induction" lacks antecedent basis. Also the phrase "which results" is ambiguous since "which" can refer to the excision or the induction. All dependent claims are also rejected.

### ***Claim Rejections - 35 USC § 112 Enablement***

7. Claims 1, 2, 4, 6-8, 10-14, and 17-18 remain rejected under 35 U.S.C. 112, first paragraph. This rejection is maintained for the reasons of record as set forth in the Office Action mailed 3 June 2004. Applicant's arguments filed 01 September 2004 have been fully considered, but are not deemed persuasive.

To the extent that the rejection was made to the scope of all host "organisms", as opposed to host "plants", the rejection is withdrawn in view of Applicant's amendments to the claims.

Applicant traverses saying primarily that many of the inductors referred to are not inductors that should be used via a gas phase (Response, p. 6). Applicant's traversal is unpersuasive. The claims are not limited to the gas phase. Only claim 2 recites the gas phase limitation.

*Working Examples:* Applicant teaches a method of obtaining scFv antibody protein from a transgenic potato plant, where the transgenic construct uses the maize anaerobically inducible GapC4 promoter operatively linked to the cDNA which codes for an scFv antibody protein, where tissue is harvested and then is induced by treatment with anaerobic conditions for 40 hours (Example 1, pages 14-16, of the specification). Applicant teaches of use of inducible recombinase systems in the specification. Example 2, p. 16-18, is titled Recombination-mediated post-harvest production in transgenic potatoes.

Applicant traverses saying primarily that the specification lists a number of available inducible promoters (Response, p. 6). Applicant's traversal is unpersuasive.

Rather this listing of inducible promoters does not comprise adequate guidance for the claimed invention. Undue trial and error experimentation would be required, having determined the host, and the induction system, to screen through and identify appropriate inducers, if chemical, which chemical(s) at what concentration, for what time duration, at what temperature, and how the chemical provided is to all the cells of the tissue, for each induction system. Additional experimentation would be necessary, having determined all the above information, to screen through a myriad of genetic regulatory systems to identify those that would function in the claimed invention. For example if a hormone induced system, what genetic regulatory systems, such as ethylene-responsive promoters/regulatory sequences are known and characterized and could function in the claimed method of obtaining a desired protein from a transgenic plant. A myriad of experimentation involving cascades of experiments dependent one upon the other would be required, to determine what host, what induction system, how to manipulate that system appropriately and what genetics components are available and would work.

***Claim Rejections - 35 USC § 102***

8. Claims 1, 2, 4, 6-8, 10 and 17-18 remain rejected under 35 U.S.C. 102(e) over US 6,194,201 B1 issued 27 February 2001, with a 102(e) date of 27 October 1998, for reasons of record. This rejection is maintained for the reasons of record as set forth in the Action mailed 3 June 2004. Applicant's arguments filed 01 September 2004 have

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been fully considered, but are not deemed persuasive. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Applicant traverses saying primarily that at no place in US 6,194,201 B1 (hereafter '201) is a post-harvest production system described (Response, p. 6). Applicant's traversal is unpersuasive. In the lack of a specific definition of "post-harvest", the term is given its broadest reasonable meaning. Webster's gives the meaning of "harvest" as being a gathered crop, and "post" means "after", therefore post-harvest is taken to mean a crop after being gathered.

Applicant further asserts that '201 teaches whole intact plant tissue and does not teach that the plant tissue has been harvested and the harvested plant tissue is then contacted with an inductor (Response, p. 7). Applicant's traversal is unpersuasive. The '201 reference teaches harvesting the plants, as discussed above, and contacting with the chemical inductor via the gas phase surrounding the harvested plant. The phrases "harvesting the plants, and contacting with the chemical inductor via the gas phase surrounding the harvested plant" are interpreted to mean making slices of the transgenic potato and inducing air-tight conditions (column 4, lines 31-36), thereby. Air-tight conditions are conditions which deoxidize the gas phase surrounding the plant. The phase "isolating the desired protein" (claim 1 (d)) is taught by '201 (column 4, lines 31-36). The desired protein (T4 lysozyme in this case) is produced after the potato is sliced and after the induction by of the GapC4 promoter by air-tight conditions. The desired protein produced is thus isolated away from plant tissue which has not been

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induced. Since no statement is made of what the "insolated" is isolated from, this physical separation is interpreted to mean isolated.

Accordingly '201 anticipates the claimed invention.

9. Claims 1, 2, 4, 6-8, 10 and 17-18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kohler et. al. (A promoter for strong and ubiquitous anaerobic gene expression in tobacco, The Plant Journal, vol. 10 , pages 175-183, 1996), for reasons of record in the Office Action mailed 3 June 2004. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Applicant traverses saying primarily that Kohler et. al. does not teach harvest the host plant or contacting the harvested plant with an inductor (Response, p. 8).

Applicant's traversal is unpersuasive. Kohler et. al. teaches harvesting a plant tissue and contacting the harvest plant with an inductor. Specifically, Kohler et. al. teaches harvesting the leaves, flowers and roots of an appropriate transgenic tobacco plant and assayed for Gus expression under aerobic conditions and after anaerobic induction (p. 178, Figures 2 and 3, and next to the last full ¶ ).

Accordingly, Kohler et. al. anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

10. Claims 1, 2, 4, 6-8, 10-14 and 17-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kohler et. al. as applied to claims 1, 2, 4, 6-8, 10 and 17-18 above, and further in view of WO 95/00555 (5 January 1995).

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Applicant traverses saying primarily that Kohler et. al. do not teach a post-harvest production and that WO 95/00555 merely describes the recombinase LBD, that the combination of the two references do not produce the claimed invention (Response, p. 8). Applicant's traversal is unpersuasive. Kohler et. al. teach post-harvest production, as discussed above. WO 95/00555 teaches a method using a LBD (ligand binding domain) recombinase system. WO 95/00555 provides motivations to combine use of the LBD-recombinase system with the method of obtaining a desired protein of Kohler et. al. (Abstract) saying that the LBD-recombinase system provides a practical means to regulate recombinase in cells and plants.

Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made. Accordingly, the claimed invention is prima facie obvious in view of the prior art.



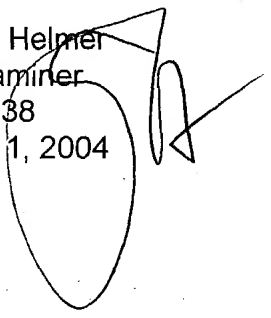
**Remarks**

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
December 1, 2004



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